REMARKS

Claims 1-7, 9-12, and 20-24 are now pending. Applicants request rejoinder of claims 20-24 upon allowance of claim 1 in accordance with MPEP § 821.04. Claim 36 was added, which is identical to claim 1 except that A^4, A^{12}, and A^{17} are not defined as Q. No new matter was added and no new issues are raised.

Applicants acknowledge that the presently pending claims are free from art.

Applicants traverse the rejection of claims 1-7, 9, 11, and 12 under 35 U.S.C. § 112, second paragraph. The Office requests clarification as to whether "A" in the formula of claim 1 at the position formerly identified as "A^5" represents alanine. Indeed, applicants have intended that the "A" represents alanine as shown, for example, in most of the examples of the peptides in Table 1 on page 7 of the present application. The Office has also objected to the presence of SEQ ID NOS:17 and 19, but it is believed that the Examiner intended to object to SEQ ID NOS:17-19. All of the sequences in the final proviso have been deleted by this amendment, therefore mooting this portion of the rejection. Thus, applicants request withdrawal of this rejection.

Applicants traverse the rejection of claims 1-7, 9, and 12 under 35 U.S.C. § 112, first paragraph (written description). Applicants respectfully submit that the particular amino acids defined in formula (1) of claim 1 or in claim 7 merely rephrase the preferred embodiments and should not be considered new matter. Applicants submit that a skilled artisan would have been "reasonably led" to the particular species as now claimed. It is respectfully submitted that the Office has not fulfilled the burden of presenting by a preponderance of evidence why a person skilled in the art would not recognize in the disclosure a description of the invention now claimed, as required by MPEP § 2163.04. The case law support applicants' position. For example, *Ex parte Sorensen*, 3 USPQ2d 1462 (BPAI 1987) stands for the proposition that the specification "need not describe the claimed invention in *ipsis verbis*" to comply with the written description requirement. In this case, the subgeneric language of "aliphatic carboxylic acid" and "aryl carboxylic acid" in the claims did not violate the written description requirement because the genus "carboxylic acid" was disclosed and five working examples, four of an aryl and one of an aliphatic carboxylic acid,

provided sufficient written description. These facts parallel the facts of the present application as described below in more detail. Please also see MPEP § 2163.05(II). The issues in the present claims are also analogous to the facts in one case, *In re Wertheim*, 541 F.2d 257, 191 USPQ 90 (CCPA 1976), where specific examples provided sufficient support to change an end point of a range, as discussed in MPEP § 2163.05(III). More specifically, although the specification in *Wertheim* did not explicitly disclose a limitation of "between 35% and 60%," the original specification included a range of "25%-60%" and specific examples included 36% and 50%. Rather, the application implicitly disclosed the species of "between 35% and 60%."

Turning to the facts in the present case, the Office rejected claim 1, alleging that A^4, A^{12}, and A^{17} defined as having a subgenus of E, D, or Q are not supported in the specification as filed. Applicants respectfully submit that E and D are acidic, as defined by example on page 5, line 16 of the present application, and fall within the definition of A^4, A^{12}, and A^{17} found on page 7, line 10 of the present application. With regard to Q, it is respectfully submitted that compound 701 (referred to as a preferred compound in paragraph [0033]) contains a Q at each position associated with A^4, A^{12}, and A^{17}. Further, almost all of the examples given in Table 1 contain an E, D, or Q in these positions. Thus, "E, D, or Q" merely identifies the preferred embodiments to which a skilled artisan would have been reasonably led, as permitted by MPEP § 2163.05. Nonetheless, although applicants do not agree with the Office's position, new claim 36 has been added which is identical to amended claim 1, but deletes Q from the definition of A^4, A^{12}, and A^{17}, and thus should be far within the limits of support found in the specification.

The Office objected to the amendments to claim 1 with respect to the particular amino acids defined in the former positions A^5, A^7, A^8, A^{11}, and A^{16}. Applicants submit that nearly every example in Table 1 contains an A at position A^5, an I at position A^7, a C at position A^8, an I at position A^{11}, and a G at position A^{16}. Thus, it is respectfully submitted that a skilled artisan would have been led to a subgenus having these amino acids at these positions. Further, page 8, line 19 identifies A^5 as preferably alanine (A), A^8 as preferably cysteine (C), and A^{16} as preferably glycine. Thus, applicants have merely included preferred amino acids as defined in the examples and the application to which a skilled artisan would have been led.

Similarly, the Office has objected to the recitation of Q at former position A^{10}. Although this position was originally defined as basic or polar neutral, almost all of the examples given in Table 1 on page 7 of the application have a Q at the former position A^{10}. Thus, there is sufficient support for a species containing a Q at position A^{10}.

Claim 1 has been similarly rejected with respect to A^{13}, A^{15}, and A^{18}, which were originally defined as aromatic amino acids. These amino acids are Y, F, and F, respectively. The application describes A^{13} as preferably tyrosine (Y) and A^{15} and A^{18} as preferably phenylalanine (F). Further, the large majority of the amino acids in the sequences defined in the table on page 7 recite Y, F, and F at these positions, respectively. Thus, it is readily apparent that the application supports the species as now recited in claim 1.

The Office objected to claim 7 as defining A^{14} as phenylalanine or tyrosine. The majority of the examples listed in Table 1 contain either a phenylalanine (F) or tyrosine (Y) at the A^{14} position. In addition, page 8, lines 4-5 indicates that preferred aromatic amino acids for A^{14} are phenylalanine and tyrosine. The Office's comment that A^{14} lacked support "outside the context of also including $A^{13, 15 \text{ and } 18}$," with respect to phenylalanine or tyrosine is not understood. There are only three naturally occurring aromatic amino acids, two of which are preferred. The application did not indicate that all of the amino acids at positions A^{13}, A^{14}, A^{15}, and A^{18} need to be either phenylalanine or tyrosine at the same time. Clarification is requested.

The Office also objected to claim 9, which defines A^6 and A^9 as lysine, histidine, arginine, glutamine, or asparagine. This claim merely defines A^6 and A^9 as naturally occurring basic (lysine, histidine, arginine defined on page 5, lines 18-19 of the present application) or neutral (glutamine, or asparagine described on page 5, line 25 of the application). Furthermore, original claim 9 defined A^6 and A^9 as the identical five amino acids as now claimed. Although A^{10}, originally present in claim 9, is now identified only as glutamine (Q), page 8, lines 12-13 of the present application describes that of the neutral polar amino acids asparagine (N) or glutamine (Q), glutamine (Q) is preferred, and asparagine (N) is less preferred. Thus, although there is not the identical disclosure of formula (1) in the application, a skilled artisan would be reasonably led to the preferred embodiments reflected in the preferred subgenus as now claimed.

The Office also objected to claim 1 with regard to the first negative proviso which excludes SEQ ID NO:13 from the formula in claim 1. Applicants intended to not only exclude SEQ ID NO:13, but also SEQ ID NOS:1 and 14 when they are naturally occurring. Many of the homologues in Table 1 have been deleted by virtue of the amendments made in the last amendment. The remainder were intended to be deleted by proviso to which the Office objects. The present application specifically discloses a preferred embodiment where the homologues are excluded from the claimed genus. The homologues as recited are in the naturally occurring L-form, as well understood by a skilled artisan. The applicants did not intend to exclude the D-forms, as discussed in paragraph [0022] on page 6 of the application. Although explicit support was not found, such explicit support is not required to fulfill the written description requirement. The written description may be fulfilled by implicit or inherent description as well, as described in the introductory paragraph of MPEP § 2163.05.

Finally, the Office objected to claim 1 with respect to the last proviso, which has been deleted, thereby mooting this rejection.

For these reasons, applicants believe the new matter rejection may be properly withdrawn.

Applicants traverse the rejection of claims 1-7 and 9-12 under 35 U.S.C. § 112, first paragraph (enablement). The Examiner points to SEQ ID NO:3 (701) as lacking viral inhibitory properties and thus alleges that "it does not appear ... that one in the art would expect that peptide [sic] that are embraced within the broad formula (1) would be expected to have antiviral properties." Nonetheless, although compound 701 may have been shown in one particular assay, at one particular concentration, under one particular set of conditions, to lack the ability to inhibit translation, this result does not suggest that a skilled artisan would be unenabled to understand that different peptides within the scope of claim 1 may have different levels of activity and, for example, higher doses of some peptides may be required to observe their effects. It is well within the capabilities of a skilled artisan to carry out routine adjustments to the conditions or concentrations to detect lower levels of activity.

Moreover, compound 701 (SEQ ID NO:3) tested positive for cell entry, as described in Table 2. Thus, it is understood that, in this particular assay, compound 701 had the potential for anti-viral activity. Example 3 suggests cell entry parallels the activity to inhibit translation, and this compound tested positive for cell entry. Thus, applicants submit that the specification enables a skilled artisan to use the invention as discussed and claimed.

The Office also alleges that the specification provides no other use for the peptides other than as viral inhibitors. However, as described in paragraphs [0012], [0046], and [0047], the peptides of the invention have been found to preferentially associate with specific tissue types, in particular, to liver. This is discussed in the present application both in terms of the possibility of targeting them to different *in vivo* locations by coupling them to other molecules which are specific to those locations, and also in terms of using the peptides of the invention to target other molecules to the liver. This ability of the peptides of the invention to preferentially associate with liver tissue can thus be used as a delivery system for specifically providing other compounds, for example, drugs, to liver tissue. The use of targeting molecules in this way is well-known in the art and, based on the teaching in the present application that the peptides of the invention are targeted in this way, a skilled artisan would expect the peptides of the invention to work with regard to this aspect.

Thus, applicants respectfully submit that the present claims are in condition for allowance, as well as the withdrawn method claims. If there are any issues outstanding, applicants request the Examiner to telephone the undersigned to facilitate allowance of this application.

CONCLUSION

In the event the U.S. Patent and Trademark office determines that an extension and/or other relief is required, applicants petition for any required relief including extensions of time and authorize the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to Deposit Account No. 03-1952 referencing docket no. 220002054822. However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

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Respectfully submitted,

By _____

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